K031690 1 of 1

JUL 0 8 2003

510(K) Summary

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	May 30, 2003
Device Trade Name:	Cynosure YAG Family Laser (PhotoGenical YAG and Acclaim)
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Devices:	Altus CoolGlide Family, ICN CoolTouch / CoolTouch II, Sciton Profile 1320
Device Description:	The Cynosure YAG Family Laser is a Nd:YAG laser, having a Nd:YAG crystal rod as the lasing medium. It is a laser with a wavelength of 1,064 nm and 1,320 nm. Laser activation is by foot switch or finger switch. Overall weight of the laser is 81 Kg, and the size is 112x48x71 cm (HxWxD). Electrical requirement is 220 VAC, 30A, 50-60 Hz, single phase.
Intended Use:	The Cynosure YAG Family Laser is indicated for permanent hair reduction and the treatment of vascular and pigmented lesions and wrinkles.
Comparison:	The Cynosure YAG Family Laser has an equivalent indication for uses, the same principle of operation, the same wavelengths and essentially the same pulse energy range as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Cynosure YAG Family Laser is another safe and effective device for permanent hair reduction and treatment of pigmented lesions and wrinkles.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 8 2003

Mr. George Cho
Senior Vice President of Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K031690
Trade/Device Name: Cynosure YAG Family Laser (PhotoGenica YAG, Acclaim)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 30, 2003
Received: June 3, 2003

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031690

Device Name: Cynosure YAG Family Laser (PhotoGenica YAG, Acclaim)

Indications For Use:

1064 nm: The Cynosure YAG Family laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, stiae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café' au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).

1320 nm: The Cynosure YAG Family laser is indicated for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles. It is also indicated for the treatment of fine lines and wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031690

Prescription Use ✓ OR Over-The-Counter Use_____

(Optional Format 1-2-96)